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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/797,157	03/09/2004	Martin Olt	DX06022 US 01	4687
28008 7590 02/27/2007 DNAX RESEARCH INC. LEGAL DEPARTMENT 901 CALIFORNIA AVENUE PALO ALTO, CA 94304			EXAMINER JIANG, DONG	
			ART UNIT	PAPER NUMBER
			1646	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/27/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/797,157

Applicant(s)

OFT ET AL.

Examiner

Dong Jiang

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 December 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 6-10 and 12-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6-9, 13 and 14 is/are rejected.
- 7) ☒ Claim(s) 10 and 12 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED OFFICE ACTION

Applicant's amendment filed on 01 December 2006 is acknowledged and entered. Following the amendment, claims 5 and 11 are canceled, and claims 1, 2, 4, 6, 8-10 and 12 are amended.

Currently, claims 1-4, 6-10 and 12-14 are pending and under consideration.

Note: according to the "Revised Format of Amendment", the status of the present claim 12 should be designated as "currently amended" (not "original") as the claim has been amended.

Withdrawal of Objections and Rejections:

All objections and rejections of claims 5 and 11 are moot as the applicant has canceled the claims.

The objection of the specification is withdrawn in view of applicant's amendment.

The objection of claims 4 and 10 for encompassing the non-elected SEQ ID NO:4 is withdrawn in view of applicant's amendment.

The rejection of claims 4, 6, 10 and 12 under 35 U.S.C. 112, second paragraph, as being indefinite is withdrawn in view of applicant's amendment.

The lack of written description rejection of claims 1-4, 6-10 and 12-14 under 35 U.S.C. 112, first paragraph are withdrawn in view of applicant's amendment.

The prior art rejection of claims 1, 2, 7-9, 13 and 14 under 35 U.S.C. 102(e) as being anticipated by Carton et al. (US 2003/0157105 A1) is withdrawn in view of applicant's amendment.

Rejections under 35 U.S.C. 112:

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 1-3, 7-9, 13 and 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, because it fails to adequately and specifically identify the "p19", from which the subject matter of the current invention was derived. The specification does not provide clear definition for "p19". In view of the prior art, the term "p19" has also been applied to indicate different subject matters including different protein substances such as p19 subunit of the transcription factor TFIIA (DeJong et al., Genes Dev., 1993, 7(11):2220-34, the abstract). It is, therefore, necessary that the applicant clearly defines the term "p19" by sufficient identifying characteristics, such as SEQ ID NO: or specific functional properties, so as to clearly and distinctly indicate the protein that is the subject of the invention. Claim 8 is similarly indefinite.

The remaining claims are included in this rejection because they are dependent from the specifically mentioned claims without resolving the indefiniteness issue belonging thereto.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3, 4, 6 and 7 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for claims limited in scope to a method of inhibiting tumor growth with the binding composition comprising an antigen binding site of an antibody to p19 of (SEQ ID NO:2 or 4) the IL-23, and a method of treating a cancer or tumor of certain types (see below for detail) with the binding composition, *does not* reasonably provide enablement for claims to a method of *modulating* tumor growth with the binding composition (claim 1, for example).

The factors considered when determining if the disclosure satisfies the enablement requirement and whether any necessary experimentation is "undue" include, but are not limited to: 1) nature of the invention, 2) state of the prior art, 3) relative skill of those in the art, 4) level of predictability in the art, 5) existence of working examples, 6) breadth of claims, 7) amount of

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direction or guidance by the inventor, and 8) quantity of experimentation needed to make or use the invention. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

The present claims encompass a method of *modulating* tumor growth with an binding composition of an antibody to p19 (claim 1, for example), which reads on *stimulating or inhibiting* tumor growth with the anti-p19 antibody.

The specification discloses two antibodies against the two subunits of IL-23, p19 and p40 (shared with IL-12), respectively, which were used in the working examples in the specification to demonstrate the tumor modulating effect. The specification demonstrates the effect of the anti-p19 antibody on inhibiting tumor growth in vivo using tumor cells generated by chemical carcinogenesis and of transformed mammary cells, and demonstrates the increase in expression of p19 or IL-23R in cancers such as colon, skin, ovary, breast and leukemia (page 27, Example IV and Table 2, and page 26, Table 1). In working example IV, the specification demonstrates that anti-p19 antibody treatment of mice with tumor resulted in a halt to increases in tumor volume, while treatment with anti-p40 antibody resulted an increase in tumor volume (page 27, [0087], and Table 2). As such, the anti-p19 antibody only *inhibits* tumor growth, not “modulates” tumor growth, which including stimulating effect (that of the anti-p40 antibody). Additionally, the specification provides no guidance or working examples indicating the “stimulating” effect of the anti-p19 antibody. Therefore, only a method of *inhibiting* tumor growth by the composition of the anti-p19 antibody, but not the full scope of “modulating tumor growth” (as recited in claim 1) would be enabled.

Due to the lack of direction/guidance presented in the specification regarding stimulating effect of the anti-p19 antibody in the claimed conditions, the absence of working examples directed to same; the presence of the opposing evidence that the anti-p19 antibody inhibits tumor growth, and the breadth of the claims which embrace both stimulating and inhibiting effect of the anti-p19 antibody, the specification does not enable any person skilled in the art to use the claimed invention in its full scope.

Conclusion:

No claim is allowed.

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Claims 10 and 12 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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Advisory Information:

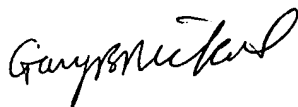
Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication should be directed to Dong Jiang whose telephone number is 571-272-0872. The examiner can normally be reached on Monday - Friday from 9:30 AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Dong Jiang, Ph.D.
Patent Examiner
AU1646
2/12/07



GARY B. NICKOL, PH.D.
SUPERVISORY PATENT EXAMINER
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